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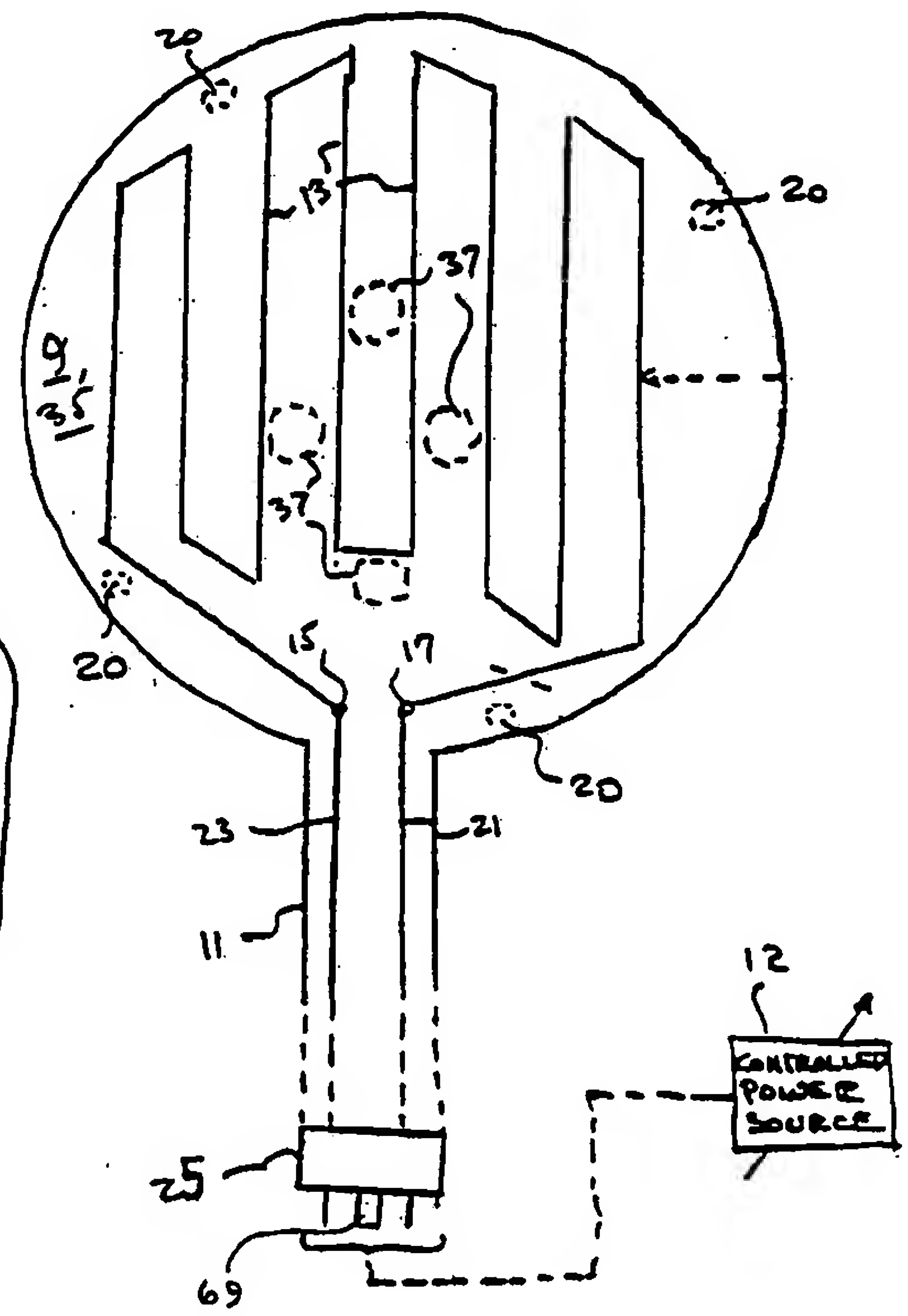
(54) Title: AUTOMATICALLY PROGRAMMABLE SELF-REGULATING DISPOSABLE ELECTRIC IMMERSION HEATER APPARATUS AND METHOD FOR MEDICAL USE

(57) Abstract

An inexpensive, disposable electric immersion heater is prepared for medical applications using a support layer (9) and an encapsulating layer (35), both of biologically compatible materials, disposed about a generally serpentine heating element (13) that is formed of an electrically resistive material which exhibits a positive temperature coefficient of resistance. The heating element (13) is operated by a power controller which senses the resistance of the heating element (13) to control the level of power supplied thereto. The terminals (15, 17) of the heating element (13) are connected via conductors (21, 23) disposed along an elongated tub (11) to a connector (25) for detachable connection to a controller power source (12). The connector (25) may include a tab (69) that retains coded information, for example, a bar code or a series of holes for optical sensing, thereon of measured parameters of the heating element (13) which may be detected upon insertion of the connector (25) into the receptacle of the controlled power supply (12) to provide programming signals that automatically set the operating parameters within which the power controller of the power supply (12) operates the heating element (13).

See p.7-9



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Automatically Programable Self-Regulating Disposable Electric Immersion Heater Apparatus And Method For Medical Use

RELATED CASES

The subject matter of this application is related to the subject matter of pending application Ser. No. 07/715,500, entitled "WARMING APPARATUS FOR MEDICAL APPLICATIONS", and to the subject matter disclosed in U.S. Patent 4,967,061.

BACKROUND OF THE INVENTION

This invention relates to apparatus for warming fluids for medical applications, and more particularly to apparatus for immersion in a fluid to be warmed that is selectively powered and sensed to assure fail-safe operation in and out of the fluid to be warmed.

Many medical procedures require warming fluids in a sterile environment at elevated temperatures that are closely regulated within a narrow range of temperatures. In addition, inexpensive, pre-sterilized, disposable equipment greatly facilitates preparation and clean-up procedures associates with a surgical procedure, and promotes the preservation of sterile conditions from patient to patient.

Electrically-controlled heaters for warming liquids or gases associated with surgical procedures have attained wide acceptance but commonly must be sterilized prior to re-use. Disposable heater units obviate the need for re-sterilization between uses, but inexpensive, single-application heaters to date have not included sufficiently high quality workmanship, materials and designs to assure reliable operation throughout an entire surgical operation. For example, safety features such as thermal cutoff switches typically do not operate satisfactorily if only a portion of an immersed heater remains in contact with a liquid to be warmed. Also, mass production techniques commonly associated with inexpensive, disposable heaters typically are incapable of maintaining close tolerances of electrical parameters to assure repeatable performance from

a population of heaters operated in a given surgical application. Such variations in electrical parameters usually contribute to difficulties in controlling the operating temperature within close tolerances.

SUMMARY OF THE INVENTION

In accordance with the present invention, inexpensive, immersible electrical heaters are mass produced with relatively low-tolerance resistance parameters including heater conductors formed of materials that exhibit positive or negative temperature coefficients of resistance. Added costs and complexities of using thermistors as heat sensors in a power controller are eliminated by using the heater conductors to sense the operating temperature. The resistance of the heater conductors is sensed during intervals of no applied power as an indication of the operating temperature in a manner that is suitable for servo controlling the supplied power. The heaters may be individually tested to determine resistance at a selected testing temperature, and may be coded with the test value of resistance in a manner that can be sensed by an electrical power controller to accurately and repeatably power each heater in a population of heaters to selected operating temperatures within close tolerances despite wide variations in resistance values from heater to heater in the population of heaters. In addition, the coding scheme on each heater facilitates automatic programming of numerous selected operating parameters of the heaters and controller.

DESCRIPTION OF THE DRAWINGS

Figure 1 is a plan view of the heater apparatus according to one embodiment of the present invention;

Figure 2 is a perspective drawing of the heater apparatus according to Figure 1 positioned within protective frames;

Figure 3(a) is a schematic diagram of one embodiment

of a power controller for the heater apparatus of Figures 1 or 2;

Figure 3(b) is a graph illustrating the operation of the circuit of Figure 3(a) during half cycles of power line signal;

Figure 4 is a perspective view of one embodiment of connector apparatus for encoding information about the heater apparatus and for detecting the encoded information to affect operation of the controller in powering the heater apparatus of Figures 1 or 2;

Figure 5 is a sectional view of one embodiment of a gas heating unit according to the present invention;

Figure 6 is a sectional view of one embodiment of a liquid heating unit according to the present invention; and

Figure 7 is a sectional view of a heater packet for applying heat, for example, to a selected region of a patient.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to Figure 1, there is shown a plan view of an immersible heater according to one embodiment of the present invention. The heater comprises a supporting layer 9 of a biocompatible material such as polyvinyl chloride or silicone rubber, generally shaped as a flat disk with a round or other suitable peripheral shape which may include an integrally formed elongated tab 11. Heater element 13 is formed thereon of a material having positive (or negative) temperature coefficient of resistance such as, for example, nickel-chromium alloy, or the like, in generally serpentine, continuous pattern between connections or terminals 15, 17. The terminals 15, 17 are connected via conductors 21, 23 which form a cable, or which may be disposed along the elongated tabs 11, to a connector 25 for detachable connection to a controlled source 12 of electrical power that regulates the power supplied to the heater 13 in the manner as later described herein. An encapsulating layer 35 of similar biocompatible material is then formed over the

supporting layer 9 to seal in the heater 13 and all associated conductors and terminals against contact with the ambient environment during sterilization or use in warming fluids. The entire sealed structure is ideally relatively flexible and may include one or more apertures 37 therethrough to promote liquid circulation around and through the structure. Flexibility of the sealed structure facilitates conforming of the heater to the shape of a confining vessel, and may facilitate extension of the elongated tab 11 (or connecting cable 11, as illustrated in Figure 2) out over the rim of a vessel that contains a volume of liquid which is to be warmed by electrical power dissipated in the heater 13.

Referring now to Figure 2 there is shown a perspective view of the heater according to Figure 2 disposed between a pair of cages or frames 41 that are oriented in spaced relationship to the upper and lower surfaces of the heater 9. These cages or frames 41 are mounted in the spaced relationship from the heater 9 by spacers 20 positioned near the perimeter of the heater 9, and an additional set of 'feet' or spacers 43 may be oriented about the perimeter of the lower cage or frame 41 to support the assembly above a supporting surface (say, the bottom of a basin). The connecting cable 11' of conductors 21 and 23 for the heater element 13 may be sealed to the heater 9 and may be sufficiently flexible to permit the convenient routing thereof over the rim of a basin.

Referring now to Figure 3(a), there is shown a schematic diagram of one embodiment of a power controller according to the present invention which measures the resistance of the heater 13 during intervals in which power is not applied to the heater to assure fail-safe operation within changing operating conditions. The material that forms the heater has a selected positive or negative temperature coefficient (TC) of resistance and therefore has a certain range of resistances over an operating range of temperatures, say, 15°C to 43°C for medical applications, that can be sensed to provide indication (via correlation

through the TC) of the temperature of the heater 13. The resistance thus sensed may be supplied to the power controller as temperature feedback information for closed-loop servo control of applied power, or for safety shutdown control against thermal runaway. The normal operating temperatures are less than the damage thresholds of the heater 13 and surrounding materials, but injury or damage may occur at elevated temperatures in excess of this temperature range due, for example, to a portion of the heater apparatus being out of contact with a liquid being warmed while the heater 13 is being powered. Thus, in Figure 3(a), amplifiers 28 and 30 are connected to operate as a differential amplifier. The input to amplifier section 28 is the voltage drop across reference resister 32, and the input to amplifier section 30 is the voltage drop across the heater 13. The following amplifier section 34, 36 operate on the output of amplifier section 28 as a precision limiter to assure that the resultant output representing current through the heater 13 (as a denominator in the following divider circuit 38) cannot become zero (or, in practice, less than .7 volts positive). The voltage signal from amplifier section 30 is applied to the divider circuit 38 as the numerator, and the current signal from amplifier section 28 is applied to the divider circuit 38 as the denominator. Of course, digital division under control of a microprocessor according to conventional technology may also be used in place of divider circuit 38. Voltage comparator 40 and reference voltage source 42 senses a rise in the voltage applied across the heater 13 to produce an output pulse 44 when the heater voltage exceeds, say 37.5 volts. This output pulse triggers latch 46 that senses whether the output 48 of the divider 38 is representative of a heater resistance above or below a selected value, say 9 ohms, for a heater of positive TC and initial value that tested at room temperature to be, for example, about 7.3 ohms. The resistance value represented at the output 48 of the divider is not constant over time, and provides only inaccurate resistance indication during one-polarity half cycle of the

power-line sine wave and near the zero crossings of the sine wave, as illustrated in the graph of Figure 3(b). The output of amplifier 40 thus establishes time marks of a period within the opposite polarity half of the sine wave during which the resistance of the heater 13 can be sampled accurately for comparison with an upper-limit value to control the shut off of applied power, or to provide servo feedback information for the proportional or direct control of applied power. If the resistance of the heater is sensed to be above the upper limit of, say, 9 ohms, then the Q output of latch 46 goes high to set latch 51. Amplifier 53 senses the Q output of latch 51 which turns on an alarm indicator 55 and turns off power transistor 57 which, in turn, releases relay 58 that turns off power supplied to the heater 13. The upper limit of allowable heater resistance may be exceeded when, for example, a portion of the heater apparatus is out of contact with liquid being heated and thereby is capable of heating to temperatures capable of damaging the materials of the heater apparatus. After the operating conditions that caused the alarm condition previously described are corrected, the heater 13 may again be powered by pressing the ON button 59 which turns on transistor 61 that re-energizes relay 58 and recycles the power-on reset circuit including amplifier 63 and latch 51. Suitable modifications or switched reconfigurations of the described circuitry may be made to detect the resistance of the heater 13 only after an extended period of no applied power to assure that the heater conductor is in substantially thermal equilibrium with the fluid being heated. Then, the sensed resistance of the heater 13 provides an indication of the temperature of the heater fluid rather than of the heater 13 for controlling a conventional temperature readout, or for further controlling power thereafter applied to the heater 13. Actual thermal equilibrium may be predicted promptly, rather than being achieved only after long delay, by sensing the heater resistance at successive brief intervals to predict the asymtotic final value (i.e. the equilibrium temperature)

from the exponential variations of resistance in successive intervals. Of course, other conventional power controller circuits, for example, including self-balancing bridge circuitry with the heater 13 connected in one circuit arm of the bridge, may also be used to assure fail-safe operation of the connected heater apparatus during changing operating conditions. Alternatively, the control circuitry described in the aforecited U.S. Patent may be modified in conventional manner to operate on the sensed resistance of the heater rather than on the thermistor signals, as disclosed therein.

In accordance with another embodiment of the present invention, a coded connector or plug, as illustrated in Figure 4, is attached to the heater apparatus for retaining coded information about the heater apparatus that can be detected by a power controller which is capable of being programmed to operate in accordance with the coded information contained in the plug. In the illustrated embodiment, the elongated tab 11 or connecting cable 11′ of the heater apparatus terminates in an attached plug 66 having a pair of conductors 65, 67 for the heater 13, and two or more electrical contacts. Specifically, the tab 69 includes a flat region capable of retaining coded information, for example, as bar codes or as rows and columns of holes 71 at selected locations that can be sensed by a mating receptacle 73 as the tab 69 and conductors 65, 67 are inserted into the receptacle. Several rows of 4-bit code may be assembled on the tab, as shown, or more complex 8-bit coding may be compacted onto the tab of any convenient length. Thus, the heater apparatus may be mass produced with low tolerances for resistance values of the heater 13 that is formed as a wire, or deposited film, or etched foil, or the like, and that is then tested at, say, room temperature to determine its initial test-value resistance which is then encoded into the tab 69 via suitable bar codes or patterns of holes 71, or the like. In addition, the temperature coefficient of resistance of the heater may be coded into the tab 69 along with data regarding other

operating parameters such as maximum allowable operating temperature, nominal allowable current and voltage values to power the heater, and the like. Thus, according to the method of the present invention, an inexpensive electrical heater for medical applications of any description (e.g. immersible heaters, hemostatic thermal scalpels, and the like) may be mass produced to low-level tolerances, and then tested accurately to establish the requisite coded information to be encoded on tab 69 regarding its electrical and operational parameters.

Then, in operation, the plug 66 is inserted into the receptacle to establish connection between the respective sets of conductors 65-75 and 67-77 in the plug 66 and receptacle 73. In the process of establishing the connections, the tab 69 enters the slot or receiving port 76 of the receptacle in alignment with rows (or columns) of optical sensors 78. These sensors include a light source or sources 79 and individual optical detectors 81 of conventional design which sense light through apertures 71 (or reflections from bar codes) as the tab 69 is inserted through the slot or receiving port 76. The coded segment of the tab 69 is preferably positioned sufficiently forward of the conductors to assure detection of the code prior to connection of the conductors. In additions, the plug 66 and receptacle may be made asymmetrical, for example, by off-setting the tab from central orientation, or by dissimilar shapes of conductors 65, 67, or the like, to assure only one orientation of the plug 66 within the receptacle 73. The detectors 81 are connected to a microprocessor-controlled power source 74 of conventional design that can sense the coded information from detectors 81 to set the operating parameters within which the connected heater will be powered and operated. Thus, the power source 74 may automatically accomodate a heater for operation at not more than 22°C at nominally 1 ampere and 20 volts, and a different heater having a different thermal coefficient of resistance for a different application may be operable up to 65°C at nominally 3 amperes and 35 volts

using the same microprocessor-controlled power source 74. In addition, time of operation, and numbers of operations, and other such operational data of a designated heater may all be encoded in the tab 69 using serial number or model number designation which are then compared with look-up table data in storage in the memory 80 to assure correct automatic setting of operating parameters for any resistance unit connected to the power source 74.

Referring now to Figure 5, there is shown a sectional view of a water-bath type of heat exchanger including a foil-type heater element 83, as previously described, disposed within a volume of water 85 that is confined within a vessel 87. A gas inlet tube 89 (e.g., for CO_2 or air) terminates below the surface level of the water and diffuses inlet gas under pressure through the water 85 which has been warmed by the heater element 83 to provide warmed, moistened gas at the outlet 91 that exhausts gas above the surface of the water 85. Of course, the vessel 87 may be formed as a sealed, flexible container, for example, of polyvinyl chloride that may be disposed of after a single use.

Similarly, with reference to Figure 6, there is shown a cross sectional view of a water-bath type of heat exchanger including a foil-type heater 91, as previously described, disposed within a volume of water 93 that is confined within a vessel 95 to surround a coil of tubing 97 that carries a gas or liquid therethrough which is to be warmed. Of course, the vessel 95 may be formed as a sealed, flexible container, for example, of polyvinyl chloride to form a heating unit that may be disposed of after a single use.

Referring now to Figure 7, there is shown a sectional view of a heater packet including a foil-type heater, as illustrated in Figure 1, immersed in a thermally-conductive gel or liquid 100 such as silicone, or bentonite or starch in water, or the like, encapsulated within a flexible container 102, for example, of polyvinyl chloride to form a convenient, controllable heat pack that may be powered by the controller circuitry of Figure 3(a) and then disposes of

after a single use. The gel or liquid 100 serves as a thermal conductor that promotes more uniform heating over the surface of the packet, and a foam-type insulating layer 103 may be provided on one face of the packet to moderate the heat available for transfer from the packet to a patient in a topical heating application, or to protect attending personnel from contact with surfaces of elevated temperature while handling the packet.

Therefore, the heating apparatus of the present invention permits inexpensive heaters having wide-ranging electrical parameters to be operated in fail-safe manner to avoid thermal runaway and damage under changing operating conditions. In addition, different electrical and operating parameters for heaters configured for different applications may be automatically sensed via encoded plugs and properly powered under tightly regulated conditions in accordance with the coded parameters.

WE CLAIM:

1. Heating apparatus for medical applications comprising:

a first layer of electrically insulating material for supporting a heater element thereon;

a heater element of electrically-conductive material disposed on said layer in a continuous pattern from one end of the pattern to another end of the pattern, the material of the element having a selected temperature coefficient of resistance;

a second layer of electrically insulating material disposed over the heater element on the first layer to form a seal with said first layer over said heater element; and

controller means disposed to connect to said one end and said other end of the pattern that forms the heater element for selectively supplying electrical power thereto in response to the resistance of the heater element that is related by the temperature coefficient of resistance to the operating temperature thereof.

2. Heating apparatus according to claim 1 wherein said first and second layers are formed of biologically-compatible material.

3. Heating apparatus according to claim 1 comprising:

plug means including a pair of conductors connected to said one and other ends of the pattern forming the heater element and including a tab thereon including code manifestations thereon indicative of a selected parameter of the heater element.

4. Heating apparatus according to claim 3 comprising:

a receptacle associated with said controller means including connectors disposed to receive the pair of

conductors for supplying thereto electrical signals for powering the heating element;

a receiving port in said receptacle for mating with and receiving therein a tab associated with a plug means; and

code sensing means disposed relative to the receptacle to detect coded information present on a tab of a plug means disposed within the receiving port of the receptacle for providing therefrom control signals representative of code manifestations on the tab.

5. Heating apparatus according to claim 4 comprising:

said controller means including control circuitry responsive to the control signals for altering a selected operating parameter in the application of electrical signal to the connectors of the receptacle in response the coded information detected on the tab of a plug means received by the receptacle.

6. method of controlling electrical heating of an element comprising the steps of:

forming a continuous pattern of electrically-conductive material capable of conducting electrical signal therethrough from one end of the pattern to another end of the pattern, the material having a selected temperature coefficient of resistance;

forming connections to the pattern of conductive material at said one and another ends of the pattern for supplying signal thereto;

measuring a selected parameter of the pattern between the connections formed on said one and another ends of the pattern;

forming code manifestations associated with the connections to the pattern that are indicative of the measured selected parameter for conveying information regarding the measured selected parameter;

establishing conductive contact with the connections to the pattern for supplying electrical signal thereto; and

sensing said code manifestations associated with the connections to the pattern during the establishing of conductive contact therewith to alter an operating parameter of electrical signal supplied to the connections.

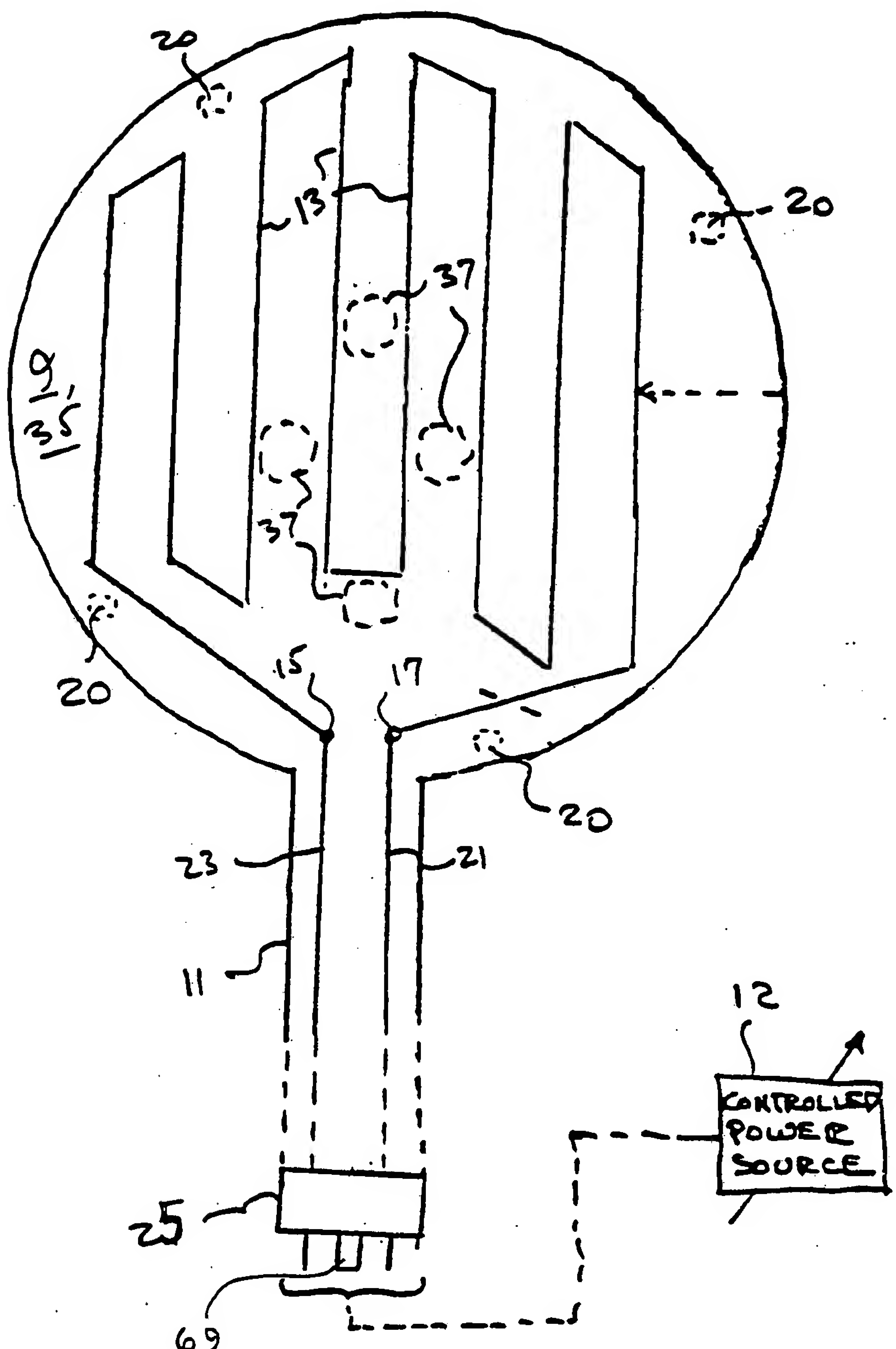
7. The method according to claim 6 wherein the step of sensing includes detecting sequential code manifestations during the establishing of connections of the pattern with associated conductive contacts.

8. The heating apparatus according to claim 1 including a container for confining a volume of liquid and said first and second layers with said heating element disposed there between immersed within the volume of liquid confined within a container to heat the liquid to a selected temperature in response to electrical signal supplied to the heating element.

9. The heating apparatus according to claim 8 comprising:

conduit means disposed within the volume of liquid within the container for passing fluid therethrough in thermally conductive relationship thereto for transferring heat from the liquid in the container to the fluid passing through the conduit means.

10. The heating apparatus according to claim 8 wherein said container includes biologically-compatible material forming a sealed enclosure about the liquid and the first and second layers immersed therein.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CONTROLLED POWER SOURCE
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FIGURE 1

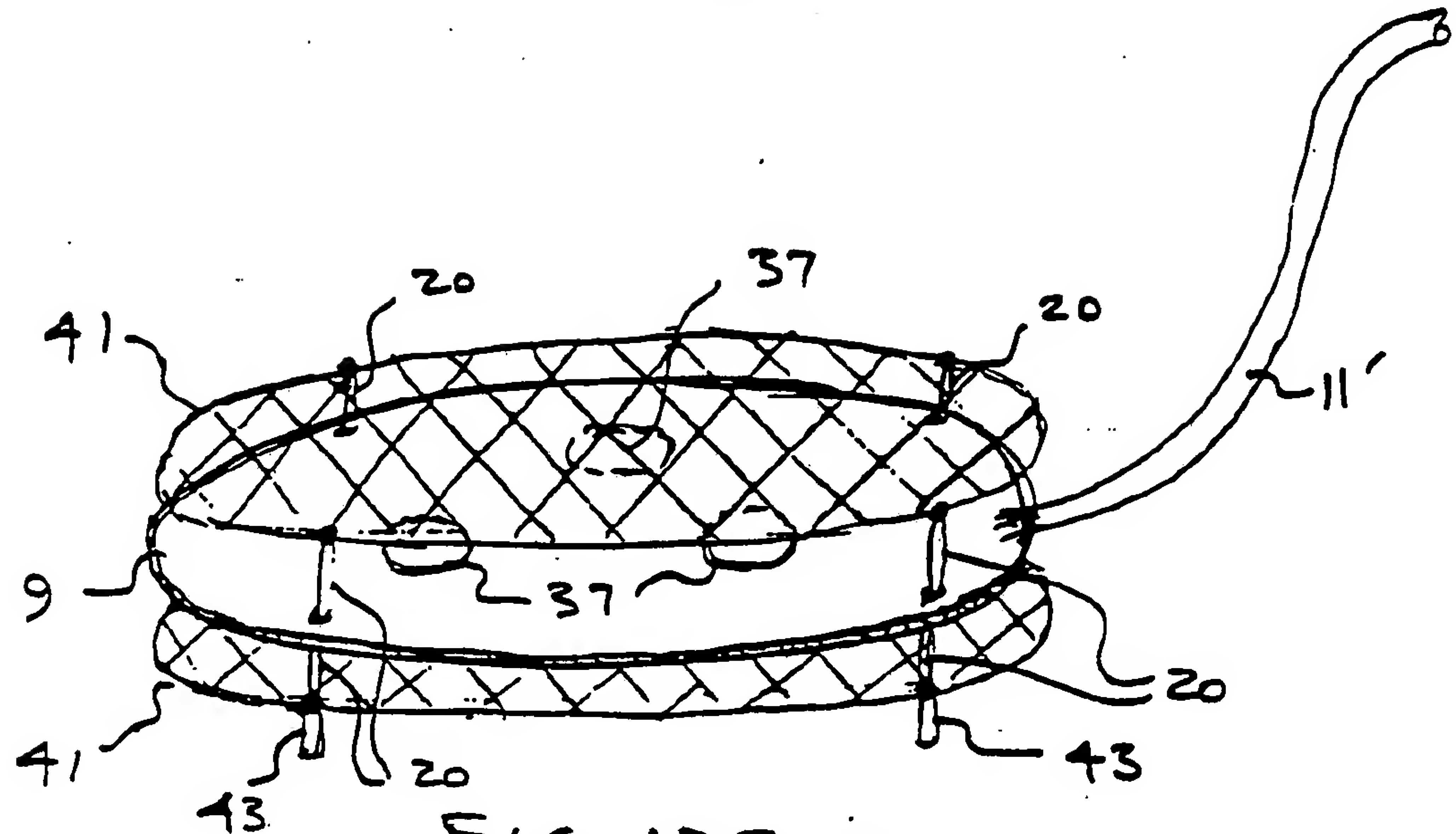

FIGURE 2

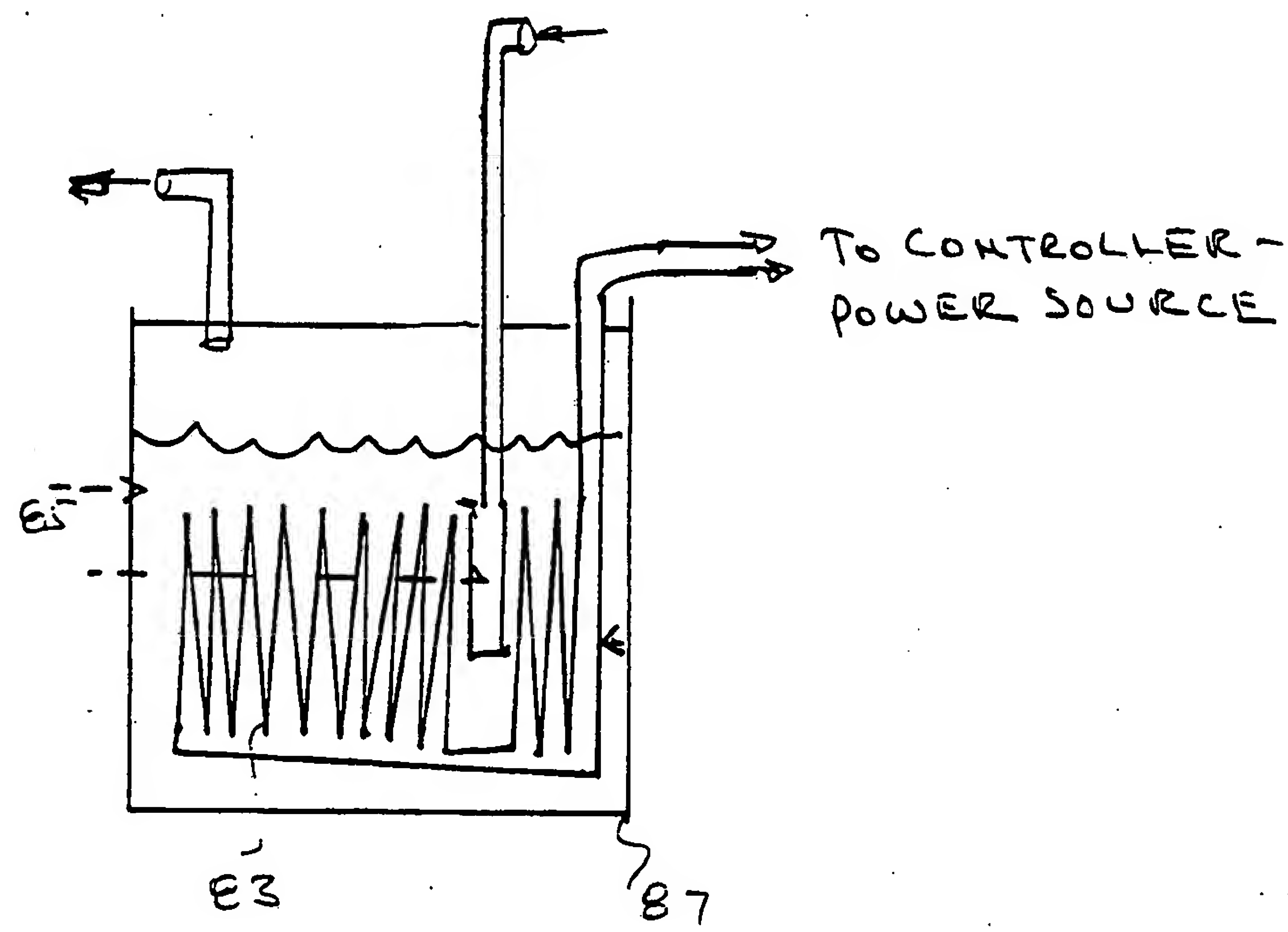

FIGURE 5

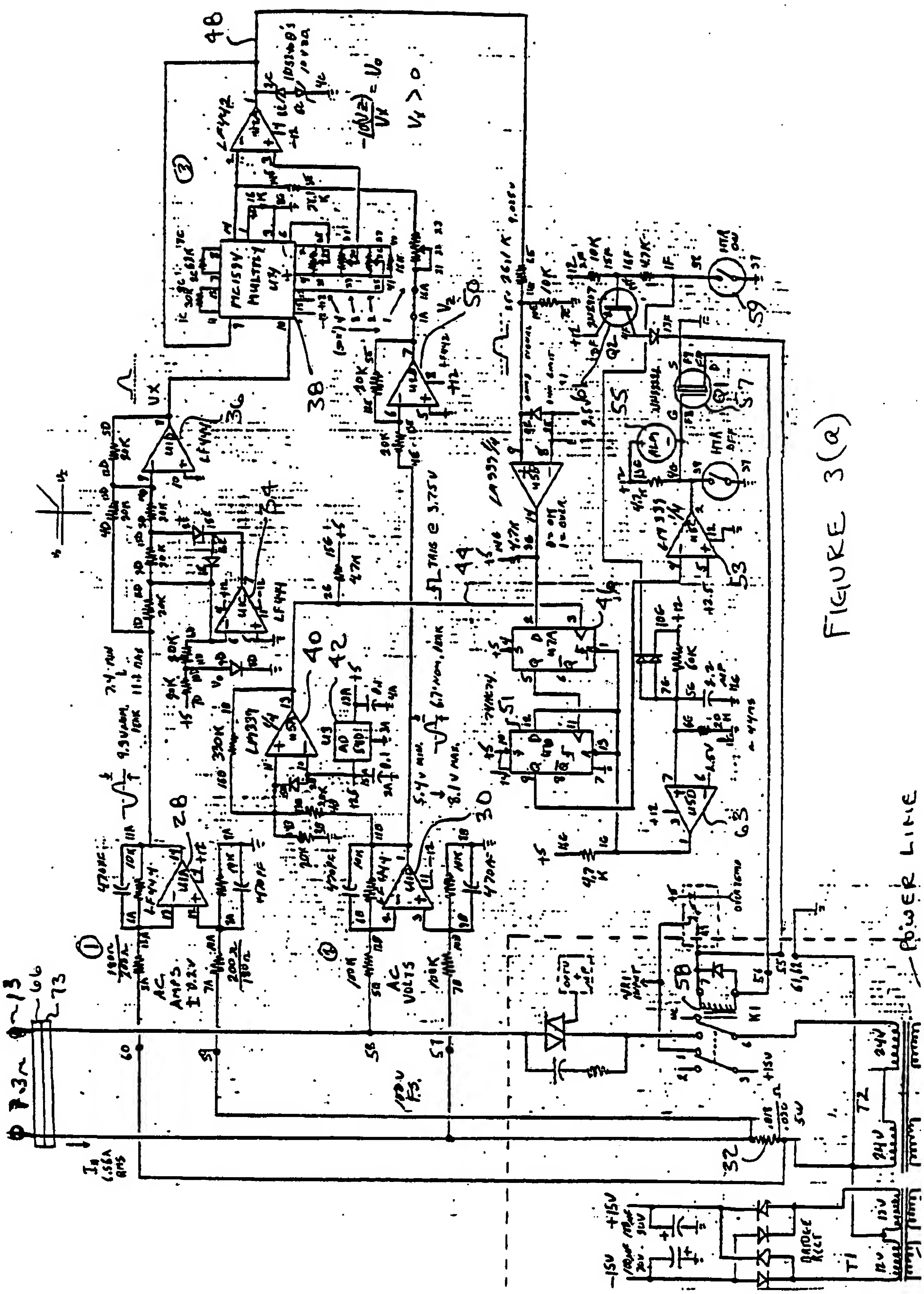

FIGURE 3(a)

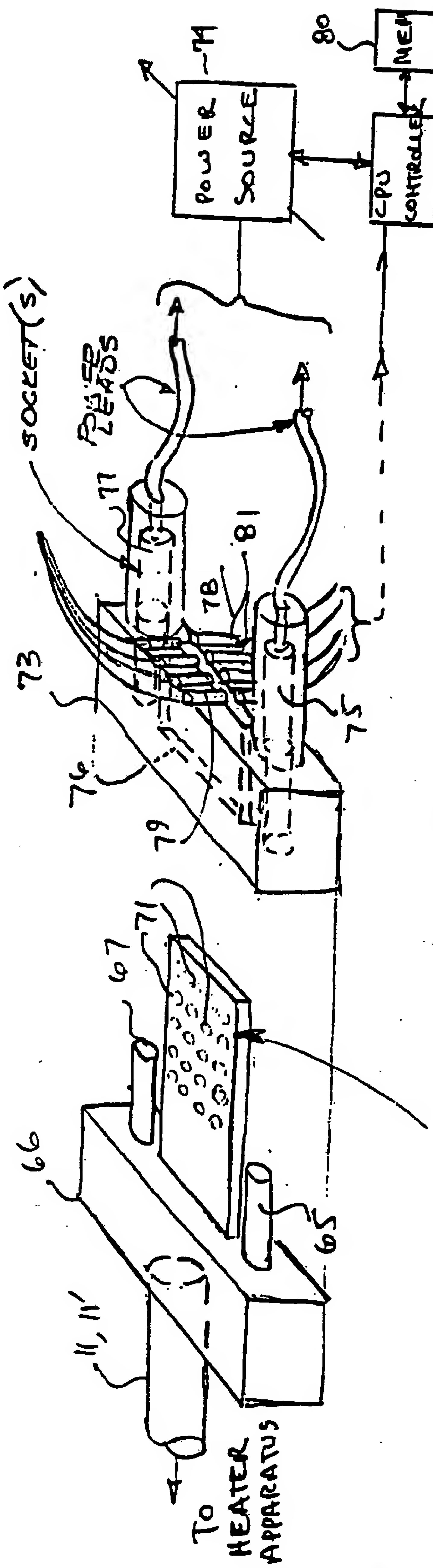

FIGURE 4

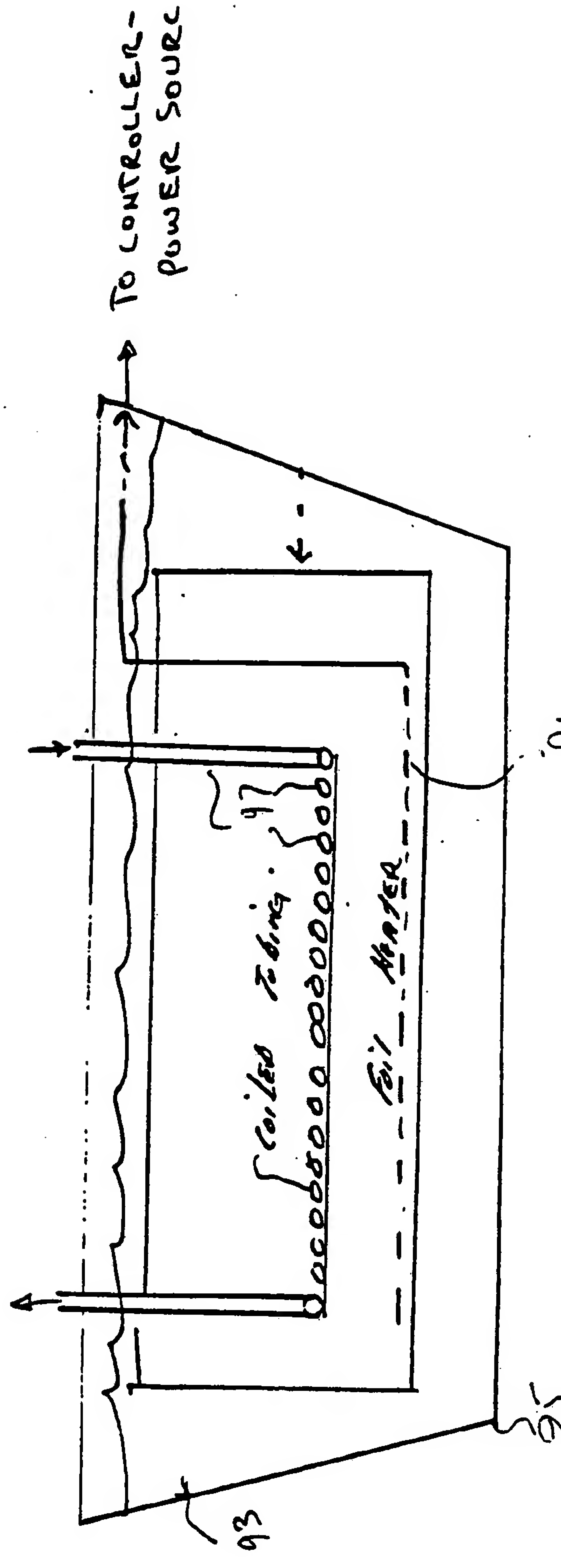

FIGURE 6

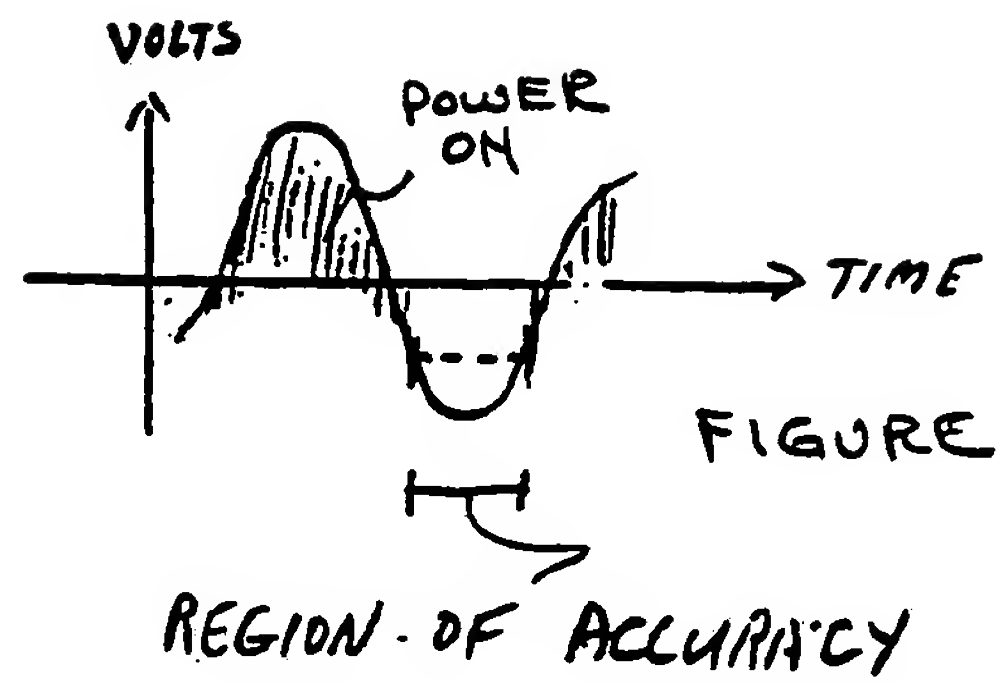

FIGURE 3(b)

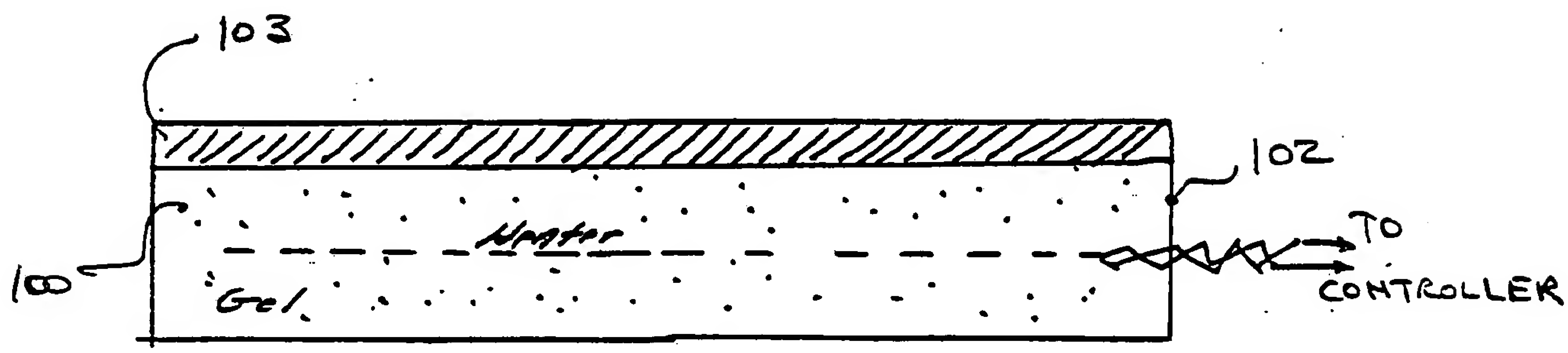

FIGURE 7

INTERNATIONAL SEARCH REPORT

PCT/US93/02301

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :H05B 1/02, 3/00, 3/80; F24H 1/22; A61F 7/00
US CL :219/499,505,506,523,548; 261/142; 392/403,443,445,481,496,503
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 219/499,505,506,523,548; 261/142; 392/403,443,445,481,496,503; 219/437,497,498,549

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 3,803,386 (RODRIGUES) 09 April 1974. See Figs. 2 and 3 and col. 1, line 49 to col. 2, line 10.	1-10
Y	US, A, 3,890,486 (FITZGERALD) 17 June 1975. See figs. 4, 5 and 9-11, and col. 1, lines 37-67.	1-10
Y	US, A, 4,086,466 (SCHARLACK) 25 April 1978. See figs. 2 and 3. and col. 1, line 60 to col. 2, line 24.	1-10
Y	US, A, 4,549,073 (TAMURA ET AL.) 22 October 1985. See fig. 1 and col. 3, line 34 to col. 4, line 23.	1-10

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 MAY 1993	9 JUL 1993

Name and mailing address of the ISA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Debbie Willen ANTHONY BARTIS
Facsimile No. NOT APPLICABLE	Telephone No. (703) 308-1147

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/02301

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,994,655 (HANDA ET AL.) 19 February 1991. See figs. 2-4 and col. 2, line 65 to col. 4, line 10.	3-7
Y	US, A, 4,642,155 (RAMSEY) 10 February 1987. See figs. 2-5 and 7 col. 2, line 41 to col. 3, line 60.	3-7
Y	US, A, 4,256,950 (WILDGRUBER) 17 March 1981. See Fig. 2 and col. 3, line 14 to col. 4, line 2.	1-8 and 10
Y	US, A, 1,110,919 (GAMBLE) 15 September 1914. See fig. 2.	8-10
Y	US, A, 2,087,586 (TISHMAN) 20 July 1937. See fig. 2.	8-10
A,P	US, A, 5,170,042 (BUNN) 08 December 1992. See figs. 1-3 and col. 2, lines 3-24.	3-7
A	US, A, 5,014,210 (POSTLEWAIT ET AL.) 07 May 1991. See col. 1, lines 5-58.	3-7